§ 107.220 Scope and effect of infant formula recalls.

(a) The requirements of this subpart apply:

(1) When the Food and Drug Administration has determined that it is necessary to remove from the market a distributed infant formula that is in violation of the laws and regulations administered by the Food and Drug Administration and that poses a risk to human health; or

(2) When a manufacturer has determined that it is necessary to remove from the market a distributed infant formula that:

(i) Is no longer subject to the manufacturer's control;

(ii) Is in violation of the laws and regulations administered by the Food and Drug Administration and against which the agency could initiate legal or regulatory action; and

(iii) Does not present a human risk.

(b) The Food and Drug Administration will monitor continually the recall action and will take appropriate actions to ensure that the violative infant formula is removed from the market.

§ 107.230 Elements of an infant formula recall.

A recalling firm shall conduct an infant formula recall with the following elements:

(a) The recalling firm shall evaluate in writing the hazard to human health associated with the use of the infant formula. This health hazard evaluation shall include consideration of any disease, injury, or other adverse physiological effect that has been or that could be caused by the infant formula and of the seriousness, likelihood, and consequences of the diseases, injury, or other adverse physiological effect. The Food and Drug Administration will conduct its own health hazard evaluation and promptly notify the recalling firm of the results of that evaluation if the criteria for recall under § 107.200 have been met.

(b) The recalling firm shall devise a written recall strategy suited to the individual circumstances of the particular recall. The recall strategy shall take into account the health hazard evaluation and specify the following: The extent of the recall; if necessary, the public warning to be given about any hazard presented by the infant formula; the disposition of the recalled infant formula; and the effectiveness checks that will be made to determine that the recall is carried out.

(c) The recalling firm shall promptly notify each of its affected direct accounts about the recall. The format of a recall communication shall be distinctive, and the content and extent of a recall communication shall be commensurate with the hazard of the infant formula being recalled and the strategy developed for the recall. The recall communication shall instruct consignees to report back quickly to the recalling firm about whether they are in possession of the recalled infant formula and shall include a means of doing so. The recalled communication shall also advise consignees how to return the recall infant formula to the manufacturer or otherwise dispose of it. The recalling firm shall send a followup recall communication to any consignee that does not respond to the initial recall communication.

(d) If the infant formula presents a risk to human health, the recalling firm shall request that each establishment, at which such infant formula is sold or available for sale, post at the point of purchase of such formula a notice of such recall at such establishment. The notice shall be provided by the recalling firm after approval of the notice by the Food and Drug Administration. The recalling firm shall also request that each retail establishment maintain such notice on display until such time as the Food and Drug Administration notifies the recalling firm that the agency considers the recall completed.

(e) The recalling firm shall furnish promptly to the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter, as they are available, copies of the health hazard evaluation, the recall strategy, and all recall communications (including, for a recall under § 107.200, the notice to be displayed at

retail establishments) directed to consignees, distributors, retailers, and members of the public.

[54 FR 4008, Jan. 27, 1989, as amended at 66 FR 17358, Mar. 30, 2001; 69 FR 17291, Apr. 2, 2004]

§ 107.240 Notification requirements.

(a) *Notification of a violative infant formula.* A manufacturer shall promptly notify the Food and Drug Administration when the manufacturer has knowledge (as defined in section 412(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act)) that reasonably supports the conclusion that an infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer:

(1) May not provide the nutrients required by section 412(i) of the act and by regulations promulgated under section 412(i)(2) of the act; or

(2) May be otherwise adulterated or misbranded.

(b) *Method of notification.* The notification made pursuant to §107.240(a) shall be made, by telephone, to the Director of the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter. After normal business hours (8 a.m. to 4:30 p.m.), contact the FDA Emergency Call Center at 866–300–4374. The manufacturer shall send written confirmation of the notification to the Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and to the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter.

(c) *Reports about an infant formula recall*—(1) *Telephone report.* When a determination is made that an infant formula is to be recalled, the recalling firm shall telephone within 24 hours the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter and shall provide relevant information about the infant formula that is to be recalled.

(2) *Initial written report.* Within 14 days after the recall has begun, the recalling firm shall provide a written report to the appropriate Food and Drug Administration district office. The report shall contain relevant information, including the following cumulative information concerning the infant formula that is being recalled:

(i) Number of consignees notified of the recall, and date and method of notification, including, for a recall pursuant to §107.200 information about the notice provided for retail display and the request for its display.

(ii) Number of consignees responding to the recall communication and quantity of recalled infant formula on hand at the time it was received.

(iii) Quantity of recalled infant formula returned or corrected by each consignee contacted and the quantity of recalled infant formula accounted for.

(iv) Number and results of effectiveness checks that were made.

(v) Estimated timeframes for completion of the recall.

(3) *Status reports.* The recalling firm shall submit to the appropriate Food and Drug Administration district office a written status report on the recall at least every 14 days until the recall is terminated. The status report shall describe the steps taken by the recalling firm to carry out the recall since the last report and the results of these steps.

[54 FR 4008, Jan. 27, 1989, as amended at 61 FR 14479, Apr. 2, 1996; 66 FR 17359, Mar. 30, 2001; 66 FR 56035, Nov. 6, 2001; 75 FR 32659, June 9, 2010]

§ 107.250 Termination of an infant formula recall.

The recalling firm may submit a recommendation for termination of the recall to the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter for transmittal to the Center for Food Safety and Applied Nutrition (HFS–605), for action. Any such recommendation shall contain information supporting a conclusion that the recall strategy has been effective. The agency will respond within 15 days of receipt by the Center for Food Safety and Applied Nutrition (HFS–605), of the request for termination. The recalling firm shall continue to implement the recall strategy until it receives final written notification from the agency that the recall has been terminated.